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PATENT -- NO FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In Re: Application of)	
PETER NASH ET AL)	
)	
Serial No.: 10/025,567)	
)	
Filed: December 26, 2001)	Group Art Unit 1644
)	
For: IMMUNOGEN ADHERENCE INHIBITOR)	Exr. P. Huynh
AND METHOD OF MAKING AND)	
USING SAME)	
)	
Case Docket No.: C150.12.3D)	

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22131-1450

Sir:

Enclosed are the original and three (3) copies of Appellants' Amended Brief under 37 CFR 1.192. The brief filing fee has been paid with the original Brief.

Appellants are individual inventors and claim small entity status.

Respectfully submitted,

PETER NASH ET AL

By

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I hereby certify that this correspondence is being deposited with the United States Postal Service
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RICHARD JOHN BAETZ
Name of applicant, assignee, or Registered Rep.

R. John Baetz
Signature

JANUARY 14, 2005
Date of Signature



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APPELLANTS' AMENDED BRIEF UNDER 37 CFR 1.192

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is in support of an appeal to the Board of Appeals from the final rejection dated January 28, 2004 of Claims 1, 3, 5-7 and 12-29. Copies of these claims are attached Appendix A.

1. REAL PARTY IN INTEREST

The real party in interest is Camas Incorporated, a Minnesota corporation having a place of business at 260 Derrynane Street, Le Center, Minnesota 56057, assignee of the invention and application.

2. RELATED APPEALS AND INTERFERENCES

U.S. Application Serial No. 09/616,843, parent application, and related Application Serial Nos. 10/038,260 and 10/039,977 are pending before the Board of Appeals and Interferences.

3. STATUS OF CLAIMS

Claims 1, 3, 5-7 and 12-29 are pending in the application.

Claims 1, 3, 5-7 and 12-29 have been rejected under 35 USC 112 and 35 USC 103(a).

No claims have been allowed.

4. STATUS OF AMENDMENTS FILED SUBSEQUENT TO FINAL REJECTION

An Amendment 37 CFR 1.116 filed on August 27, 2004 has not been entered.

5. CONCISE SUMMARY OF THE INVENTION

The invention is directed to a microbial adherence inhibitor, in the form of chicken egg antibodies, for substantially preventing the attachment or adherence of colony-forming immunogens or haptens in the rumen and intestinal tract of host food animals and living beings. The inhibitor promotes the growth of food animals by improving feed conversion rates by decreasing the waste of dietary protein caused by the presence of certain colony-forming protein-wasting organisms in food animals.

Common bacterial immunogens which cause dramatic decreases in an animal's ability to utilize dietary protein include but are not limited to *Peptostreptococcus anaerobius*, *Clostridium aminophilum*, and *Clostridium sticklandii*. These organisms have been collectively primarily responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as \$25 billion annually to cattle producers and is especially apparent in grazing animals which are often deficient in protein, even though their protein intake appears to be adequate. As the host consumes protein in the diet, these deleterious organisms wastefully degrade the protein to ammonia which is converted to urea by the liver and kidneys and thus lost to the host when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host needs for the efficient utilization of ammonia.

The young of chickens receive passive antibody protection through the store of antibodies placed in the eggs in which they develop from the embryonic stage. Chickens, in particular, have the ability to "load up" their eggs as they are formed, with a very large supply of antibodies concentrated many fold over that which is present in the serum of the hen. In addition, chicken antibodies are much more stable and resistant to inactivation through digestion than mammalian antibodies, especially under adverse

conditions. Once immunized the hen layers the unique IgY type immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin IgM and IgA immunoglobulins help resistance to the whole egg preparations and help protect the avian antibodies. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens. Furthermore, the large quantities of antibodies which are placed in eggs are much more exclusively those specific for the antigens to which the chicken has most recently been exposed to and challenged by. This all results in the eggs of chickens being a most ideal source for large quantities of economically produced, highly specific and stable antibodies.

The microbial adherence inhibitor for administration to host food animals to inhibit the adherence of colony-forming immunogens in the rumen and/or intestinal tracts of the food animals is produced by the method of first inoculating female chickens, in or about to reach their egg laying age, with the particular target immunogen. Then, after a period of time sufficient to permit the production in the chicken of antibody to the targeted immunogen, the eggs laid by the chickens are harvested. The total antibody-containing contents of the eggs are separated from the shells and dried. The dried separated egg antibody adherence inhibiting material may be stored or shipped for use when needed. The dried egg contents incorporating the antibody specific to the targeted immunogen is administered to the food animals by distributing the antibody material substantially uniformly throughout an animal feed and then supplying the resulting antibody-containing animal feed to the food animals. The antibody-

containing animal feed is supplied to food animals during the normal finishing schedule prior to slaughter. The substantial prevention of colonization of the targeted organism in the rumen or intestinal tract of the animal will ultimately permit elimination of the organism from the animal. This repression of colonization and elimination of the subject organisms will permit a significant decrease in wasteful degradation of the dietary protein fed to food production animals. In addition, the resulting decrease in competition to the non-ammonia producing organisms will further enhance the most efficient utilization of feed by the host.

The specification including the claims define the microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The control of growth of the colony forming wasting immunogen in the animal boosts feed efficiency and promotes growth of the animal. The target protein wasting immunogen is from a class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilum*. These immunogens are described in Examples 7, 8 and 9 on pages 16-18 of the specification.

Examples 17, 18 and 19 also relate to these immunogens. *Specification, pages 21-22.*

Organisms that colonize in the rumen and digestive tract of a host animal must possess the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 8, lines 19-20.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, lines 1-3.* Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification, page 10, lines 2-4.* The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 10, lines 4-5.* The organism inhibitor is the colonizing

microorganism adhesion inhibitor that is chicken antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 12, lines 11-13.* The albumin IgM and IgA immunoglobulins bind in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

An alternate embodiment of the microbial adherence inhibitor includes the method of coating of carrier material with the whole egg yolk and albumin. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard animal feeds. *Example 21, page 23.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk and albumin immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The coated carrier material increases the duration of the effectiveness of the IgY, IgM and IgA immunoglobulins.

A further embodiment of the microbial adherence inhibitor includes the use of coating the mixed whole egg yolk and albumin on dry carrier material to dry the egg yolk and albumin. A

separate drying process is not used prior to coating of the carrier material with the egg yolk and albumin. The elimination of a separate drying step increases the effectiveness of the immunoglobulins in inhibiting adherence immunogens in the intestinal tracts of animals.

6. CONCISE STATEMENT OF ALL ISSUES PRESENTED FOR REVIEW

A. Whether Claims 1, 3, 5-7 and 12-29 are unpatentable under 35 USC 112 because the specification does not enable a person skilled in the art to make and use the invention.

B. Whether Claims 1, 3, 5-7 and 12-29 are unpatentable under 35 USC 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

C. Whether Claims 5, 6, 7, 12 and 22-29 are unpatentable under 35 USC 112 as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

D. Whether Claims 1, 3, 5, 13, 16 and 19 are unpatentable under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489* and *Krause et al*.

E. Whether Claims 14, 15, 17, 18, 20 and 21 are unpatentable under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489*, *Krause et al*, *Adalsteinsson '878* and *Betz et al '867*.

F. Whether Claim 5 is unpatentable under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Sugita-Konishi et al* and *Yokoyama et al*.

G. Whether Claims 6, 7, 12, 22 and 23 are unpatentable under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Sugita-Konishi et al*, *Yokoyama et al*, *Adalsteinsson et al '878* and *Betz et al '867*.

H. Whether Claims 24-29 are unpatentable under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Krause et al*, *Adalsteinsson et al '878* and *Betz et al '867*.

7. GROUPING OF CLAIMS

The claims fall into three groups. The claims of Groups I, II and III do not stand or fall together. Each group of claims define a distinct and novel microbial adherence inhibitor for inhibiting adherence of colony-forming immunogens in the rumen and intestinal tracts of food animals and living beings.

Group I comprises Claims 1, 3, 5, 13, 16 and 19. These claims define a microbial adherence inhibitor that promotes the growth of food animals by decreasing the waste of dietary protein caused by the presence of targeted colony-forming protein-wasting immunogens. The protein-wasting immunogens are from the class consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilium*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The inhibitor is produced by a method that includes drying of the entire contents of eggs having yolks with IgY and albumin IgM and IgA immunogens. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens.

Group II comprises Claims 14, 15, 17, 18, 20 and 21. These claims include the subject matter of parent Claims 13, 16 and 19 and the process of drying the entire contents of the eggs having yolk IgY and albumin IgM and IgA immunoglobulins by coating dry feed carrier material with the entire contents

of the eggs. The dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beat pulp. The coated carrier material increases the duration of the effectiveness of the IgY immunoglobulins and facilitates mixing with standard animal feeds.

Group III comprises Claims 6, 7, 12, 22 to 29. These claims define a microbial adherence inhibitor produced by the method of promoting the growth of food animals by decreasing the waste dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of the immunogen to multiply, the immunogens include P antigen from *P. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilum*. The method includes providing a dry feed carrier material, coating the dry feed carrier material with the antibody and albumin of the harvested eggs. The carrier material coated with the antibody yolk and albumin is distributed substantially uniform in animal feed. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens. The method does not include a separate step of drying the antibody yolk and albumin as required by the inhibitor of Claims 14, 15, 17, 18, 20 and 21.

8. ARGUMENT

A. Rejection of Claims 1, 3, 5-7 and 12-29 under 35 USC 112 on the basis that the specification does not enable a person skilled in the art to which it pertains to make and use the invention commensurate in scope with these claims

The specification of the application complies with the requirements of 35 USC 112.

Under 35 USC 112 ¶ 1 "[t]he specification shall contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification clearly discloses Appellants' microbial adherence inhibitor produced by the method of promoting the growth of living beings including food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals, hosts and living beings.

The Examiner has construed the requirements of 35 USC 112 to include any person skilled in the art to make and use the invention commensurate in scope with the claims. *Office action 6/03/2003, page 3, lines 26-28*. This is not the requirement of 35 USC 112 ¶ 1. It is the specification, according to 35 USC 112 ¶ 1, that contains the written description to enable a person skilled in the art to make and use the same.

The specification describes the methods of Selection of Egg laying avian hens, pages 12-13; Preparation of Stock Culture, page 12; Preparation of H antigens for Immunogens, pages 13-14; Preparation of O antigens for immunogens, pages 14-15; Preparation of A antigen for immunogen, pages 15-16; Preparation of P antigen for immunogen, pages 16-17; Preparation of CA antigen for immunogen, pages 17-18; Analysis of individual eggs and serum over time, page 19; Immunization of chickens with immunogens, page 20-22; and Feeding of Cattle, pages

27-28. The specification contains a detailed description and best mode of Appellants' process of promoting the growth of food animals, such as cattle, by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of the animals to reduce the ability of the immunogen to multiply. This description enables a person skilled in the art to make and use the subject microbial adherence inhibitor.

B. Claims 1, 3, 5-7 and 12-29 contain subject matter described in the written description of the specification which enables one skilled in the relevant art to make and use the subject matter of the invention.

The Examiner contends that the specification does not provide a written description of any microbial adherence inhibitor for administration to food animals that inhibit the adherence of any colony-forming immunogen in the rumen or intestinal tracts of food animals.

Claims 3, 5, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 24, 25, 26, 27, 28 and 29 do not include any microbial adherence inhibitor. The claims are limited to at least one of a colony-forming immunogen from the class consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilium*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The written description of the specification is in clear, concise and exact terms with respect to these colony-forming immunogens. A person skilled in the relevant art can readily make and use the claimed microbial adherence inhibitor according to written description of the invention. The rejection of Claims 3, 5, 12-21 and 24-29 based upon 35 USC 112 should be reversed.

Claims 6 and 22 define a microbial adherence inhibitor for administration to food animals to inhibit adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of the food animals. The immunogen is limited to a colony-forming immunogen.

Appellants have provided a representative number of species of colony-forming protein-wasting immunogens to describe the genus identified by the terms target colony-forming

immunogen. These immunogens are well known protein-wasting immunogens. The species of immunogens are identified from a class consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. Appellants have also disclosed other colony-forming organisms including Actinomycetes, Streptococcus, Bacteriodes such as *B. ruminicola*, Cryptococcus and yeast molds. *Specification, paragraph 0006, lines 1-2*. This class is sufficient to identify a genus of like immunogens to a person skilled in the art. One skilled in the art would be aware of the bacterial antigens noted by *Stolle et al '018* in column 5, lines 5-35. Claims 1, 3, 5, 6, 7 and 12-29 particularly point out and distinctly claim the subject matter of Appellants' microbial adherence inhibitor as described in the written description of the specification.

The Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Page 12, lines 11-13*. The particular language is the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins." This function is supported by the disclosure that hen layers the unique IgY types immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification page 10, lines 4-5*. The whole egg preparation includes the IgY immunoglobulins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the finding of IgY immunogens to the protein-wasting immunogens as more IgY immunogens are available to find to the protein-wasting

immunogens.

The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

Appellants have discovered that egg IgY immunoglobulins must bind to protein-wasting immunogens to inhibit adherence of the immunogens in the intestinal tracts of hosts and animals. The totality of the teachings of the prior art do not reveal this discovery and advantageous results.

Appellants have conducted bead studies to demonstrate that antibodies disclosed in the application bind to bacteria. Bead studies were used because they can be seen more clearly. The beads are activated and then coated with antibodies from specific egg products disclosed in the application. The binding action of egg immunoglobulins is illustrated in Exhibits A to D. The binding action of the egg immunoglobulins to Appellants' claimed microbial adherence inhibitor is a discovery beyond the teachings of the prior art.

C. Claims 5, 6, 7, 12 and 22-29 contain subject matter that is described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

The Examiner has characterized this as a new matter rejection. The Examiner contends that the terms "living being" departs from the specification as originally filed. The specification

describes the microbial adherence inhibitor used for food animals and hosts to inhibit adherence of colony-forming immunogens in the rumen and intestinal tracts. The hosts and animals are living beings as they are alive and exist. The terms living being is not indefinite. The term hosts is included in the specification. *Paragraph 0027, lines 1-2; paragraph 0066, lines 1-2.* The terms "living beings" as the live hosts in Claim 12 is not new matter to this claim.

Claim 6, line 14, has been corrected to change "living being" to --food animals--. This correction conforms to the food animals defined in line 1 of the claim.

Claim 22, line 14, Claim 24, line 16, Claim 26, line 18 and Claim 28, line 18, have been corrected to change "living beings" to --food animals--. This correction conforms to the food animals defined in line 1 of these claims.

The rejection of Claims 6 and 22-29 under 35 USC 112, new matter, does not apply to these claims as the corrected claims do not contain the terms "living beings". The food animals are living beings and hosts.

Appellants have provided a representative number of species of colony-forming protein-wasting immunogens to describe the genus identified by the terms target colony-forming immunogens. These immunogens are well known protein-wasting immunogens. The species of immunogens are identified as from a class consisting of: *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. This class is sufficient to identify a genus of like immunogens to a person skilled in the art. One skilled in the art would be aware of the bacterial antigens noted by *Stolle et al '018* in column 5, lines 5-35. Claims 1, 3, 5, 6, 7 and 12 to 29 particularly point out and distinctly claim the subject matter of Appellants' microbial adherence inhibitor as described in the specification.

D. Rejection of Claims under 35 USC 103

§ 103 Conditions for patentability; nonobvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 USC 103(a)

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiry comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

The Federal Circuit has also made it clear that the showing of a motivation to combine two or more references must be "clear and particular". See for example *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 202 F.3d 1340 (Fed. Cir. 2000), where the Federal Circuit stated:

When an obviousness determination is based on multiple references, there must be a showing of some "teaching, suggestion, or reason" to combine references. [Citation omitted].

Although a reference need not expressly teach that the disclosure contained therein should be combined with another, [citation omitted] the showing of combinability, in whatever form, must nevertheless be "clear and particular."

As the Federal Circuit also stated:

"The factual inquiry whether to combine references must be thorough and searching" *Id.* It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.

In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002).

It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989). The prior art must provide a suggestion to make the combination with structure shown and claimed. *CR Bard Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998).

The Examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. He can satisfy this burden *only* by showing some objective, clear and particular teachings in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

It is submitted that the prior art of record does not contain a clear and particular motivation to combine the references as opined by the Examiner.

The primary reference in all of the rejections based upon 35 U.S.C. 103(a) is U.S. Patent No. 5,080,895 (*Tokoro '895*)

Tokoro '895 discloses a method of inhibiting diarrhea in animals with bird antibody IgY

using the yolks, albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herders to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro '895* is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in *Tokoro '895* of an IgY immunoglobulin that binds to colony-forming illness-causing immunogens. The antibody containing substance also is used as a nutrition supplement, and as an additive to food animals. *Tokoro '895* does not provide a teaching of a method for reducing or eliminating the incidence of illnesses caused by colony-forming illness-causing immunogens by binding egg IgY immunoglobulins combined with IgM and IgA immunoglobulins to illness-causing immunogens to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply and colonize.

Tokoro '895 does not coat a dry feed carrier with a mixed egg yolk and albumin product.

The object of the *Tokoro '895* disclosure is to administer to animals affected by an intestinal infection disease for therapeutic purposes. *Column 4, lines 1-4*. The *Tokoro '895* substance is also useful in the treatment of various infectious diseases, additives in food for livestock, cosmetics and medicines. *Column 4, lines 16-21*. Appellants' claimed microbial adherence inhibitor is not a treatment of a disease in animals. Appellants' microbial adherence inhibitor is the prevention of illnesses in humans by eliminating the illness-causing immunogens in animal meat. Appellants have discovered a new and useful microbial inhibitor for preventing, as opposed to treating, illnesses in humans caused by a colony-forming illness-causing immunogen.

The Examiner has acknowledged that the teachings of *Tokoro '895* do not include "the method wherein the antibody in the eggs including IgY immunoglobulins in the yolks of the eggs

whereby the IgY immunoglobulins bind to a targeted colony-forming illness-causing immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted-colony forming illness-causing immunogen in the intestinal tract of the animals." *Office Action of July 28, 2004, page 7, lines 9-14, Application Serial No. 10/039,977.*

The separate and combined teachings of the second references, *Kaspers et al*, *Sugita-Konishi et al*, *Krause et al*, U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 5,741,489 (*Pimental*), U.S. Patent No. 4,748,018 (*Stolle et al*), *Yokoyama et al* and U.S. Patent No. 4,166,867 (*Betz et al*) with *Tokoro '895*, do not suggest to one skilled in the art the binding of IgY immunoglobulins to illness-causing immunogens and that this binding is helped or assisted and increased by the IgY and IgA immunoglobulins. There is no clear and particular motivation for a person skilled in the art to combine these references. Further, any combination of these references would not product Appellants' claimed microbial adherence inhibitor.

E. Rejection of Claims 1, 3, 5, 13, 16, 19 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489* and *Krause et al*.

Claims 1 and 5 define a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of living beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

Claim 3 depends upon Claim 1. Claim 3 further defines the targeted colony-forming immunogen as being from the class consisting of *P. anaerobius*, *C. sticklandii* and *C.*

aminophilium.

Claims 13, 16 and 19 define a microbial adherence inhibitor for promoting growth of food animals by decreasing waste of dietary protein caused by protein-wasting immunogen. The entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. The protein-wasting immunogens are identified as P antigen from *P. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilium*.

Tokoro '895 discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdpersons to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro '895* is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in *Tokoro '895* of an IgY immunoglobulin that binds to a colony-forming immunogen. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. *Tokoro '895* does not provide a teaching of a microbial adherence inhibitor produced by the method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, and CA antigen from *C. aminophilium*, to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

The *Kaspers et al* publication discloses the transfer of maternal antibodies into the egg of a chicken and subsequent transport thereof into a developing embryo. There is no disclosure in the *Kaspers et al* publication of IgY, IgM and IgA immunoglobulins whereby the IgY immunoglobulins bind to colony-forming or protein-wasting immunogens with the binding process being assisted by the IgM and IgA immunoglobulins thereby inhibiting the colony-forming or protein-wasting immunogens from adhering to the intestinal tracts of animals.

Pimental '489 discloses a method for increasing feed conversion efficiency in mammals with a diet containing an antibody produced using the enzyme urease as the antigen. *Pimental '489* states that chicken antibodies are generally known to protect the recipient against bacterial infections. No antibody has been shown to increase feed conversion efficient. *Col. 2, lines 59-63. Pimental '489* is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching in *Pimental '489* of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Krause et al does not disclose or suggest that IgY immunoglobulins bind to protein-wasting immunogens and that IgM and IgA immunoglobulins assist and help the binding process.

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. *Krause et al* discovered that monensin inhibited growth of *P. anaerobius* and *C. sticklandii* in the rumen of an animal but did not inhibit *C. aminophilium*. The result was the

reduction in the amount of ammonia in the rumen and reduction of environmental pollution.

There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an animal. U.S. Patent Nos. 3,501,568 and 3,797,32 are directed to the use of monensin for promoting growth and feed efficiency of food animals. Monensin can be toxic to some animals. Feed intake of the animals is reduced as monensin cannot be added to molasses. *Specification, page 5, lines 4-12.*

It is submitted that Appellants' microbial adherence inhibitor produced by the method of promoting the growth of food animals as defined in Claims 1, 3, 5, 13, 16 and 19 is patentable in view of the individual and combined teachings of *Tokoro '895* in view of *Kaspers et al, Pimental '489* and *Krause et al.* Further, there are no motivating directions or suggestions in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

There are insufficient teachings of the above combined references and no evidence of a motivating force which would impel one skilled in the art to make and use the microbial adherence inhibitor produced by the claimed method. The numerous rejections of the claims is evidence that one skilled in the art would not determine that it is obvious to make a microbial adherence inhibitor by the method of using IgY, IgM and IgA immunoglobulins in the entire contents of eggs to bind the IgY immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. The

binding process is assisted and helped by the IgM and IgA immunoglobulins. The Examiner has completely failed to show any motivation to combine his references, either the *Tokoro '895* reference with the *Kaspers et al* reference, the *Pimental '489* reference and the *Krause et al* reference. There is certainly no "clear and particular" showing of motivation to combine.

F. Rejection of Claims 14, 15, 17, 18, 20 and 21 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Krause et al*, *Adalsteinsson '878* and *Betz et al '867*

Appellants' analysis, *supra*, of the primary reference, *Tokoro '895* and secondary references, *Kaspers et al* and *Krause et al*, are applicable to this rejection.

Claims 14, 15, 17, 18, 20 and 21 are claims dependent upon parent Claims 13, 16 and 19. The parent Claims 13, 16 and 19 include the method of drying the entire contents of the eggs. The dependent Claims 14-15, 17-18 and 20-21 more particularly define the drying process. The drying of the separated entire contents of the eggs is achieved by coating the dry feed carrier material with the entire contents of the eggs. Parent Claims 13, 16 and 19 define the method of promoting growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilum*, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method of Claims 14-15, 17-18 and 20-21 includes the step of drying the separated entire contents of the harvested eggs with dry feed carrier material. The moisture of the entire harvested eggs on the dry feed carrier material is absorbed by the carrier material. This avoids the reduction of the effectiveness of IgY, IgM and IgA immunoglobulins caused by a separate drying process to dry the entire contents of the harvested eggs before coating the dry carrier material with said contents of the eggs.

Adalsteinsson et al '878 disclose a method of administering to animals an effective

amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directly onto food pellets. *Col. 9, lines 31-39*. This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Appellants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is distributed into the animal feed. The animal feed mixed with the coated carrier material is supplied to the animals. The carrier material is defined in Claims 15, 18 and 21 as a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

Betz et al '867 disclose a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody.

Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a carrier material with IgY antibody as defined in Claims 14, 17 and 20.

In view of the absence of a teaching of the claimed drying of antibody yolk and albumin with a dry feed carrier by *Betz et al '867* and *Adalsteinsson et al '878*, it would not have been obvious to a person skilled in the art to make and use the inhibitor claimed in Claims 14-15, 17-18 and 20-22.

Further, the Examiner has failed to show any motivation to combine his references. There is certainly no "clear and particular" showing of motivation to combine the numerous references based on objective evidence of record.

G. Rejection of Claim 5 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Sugita-Konishi et al* and *Yokoyama et al*

The remarks concerning *Tokoro '895*, *Kaspers et al* and *Pimental '489* are applicable to this rejection.

Claim 5 defines a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of live beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

Stolle et al '018 discloses a method of passive immunization of mammals using avian egg yolk antibody against any of a variety of antigens using various methods of administration under various conditions and using various compositions incorporating the antibody, after first developing in the mammal a tolerance for the antibody. The *Stolle et al* method of passive immunization of a mammal has two steps. First, the mammal is fed a material having a heterologous protein antibody obtained from the egg of a fowl immunized against an antigen until the mammal develops substantial tolerance to the antibody. Second, the mammal is administered an antibody obtained from a fowl immunized against the antigen. There is no disclosure in *Stolle et al '018* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. Furthermore, *Stolle et al '018* does not disclose or suggest to one skilled in the art that the binding process is assisted or helped by IgM and IgA immunoglobulins.

The *Sugita-Konishi et al* publication discloses IgY immunoglobulins from egg yolk from hens immunized with an infections pathogen is efficient in prevention of the disease caused by the pathogen. The IgY immunoglobulin was isolated from the egg yolk of hens immunized with 26 strains of bacteria. The investigation of the function of isolated IgY immunoglobulin was limited to three infectious bacterial strains. There is no disclosure in *Sugita-Konishi et al* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and that the binding process is assisted or helped by IgM and IgA immunoglobulins.

The *Yokoyama et al* publication discloses isolation of antibodies from chicken egg yolk. Immunoglobulin G (IgG) egg yolk was diluted with distilled water and mixed with ethyl alcohol. The mixture was centrifuged. The supernatant which contained the IgG was purified. This process does not suggest Appellants' microbial adherence inhibitor produced by the method defined in Claim 5. There is no disclosure in *Yokoyama et al* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and the binding process is assisted or helped by IgM and IgA immunoglobulins.

Further, the Examiner has again failed to show any motivation to combine his references. There is no "clear and particular" showing of motivation to combine the numerous references based on objective evidence of record.

H. Rejection of Claims 6, 7, 12, 22 and 23 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Sugita-Konishi et al*, *Yokoyama et al*, *Adalsteinsson et al '878* and *Betz et al '867*

Appellants' analysis, *supra*, concerning the primary reference, *Tokoro '895*, and secondary

references, *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Sugita-Konishi et al*, *Yokoyama et al*, *Adalsteinsson et al '878* and *Betz et al '867*, are applicable to this rejection.

Claims 6, 12 and 22 define the microbial adherence inhibitor as including a dry feed carrier material. The dry feed carrier material is coated with the separated entire contents of the harvested eggs. The dry food carrier material coated with the entire contents of the eggs inhibits the adherence of colony-forming immunogens in the digestive tracts of animals by binding IgY immunoglobulins to the colony-forming immunogens and assisting or helping the binding process with IgM and IgA immunoglobulins. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 23*. The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The carrier material flows with the animal feed down the animals' digestive tracts exposing the IgY, IgM and IgM to colony-forming immunogens therein.

Claim 12 further defines the colony-forming immunogens as being from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

Claim 7 depends upon Claim 6 and Claim 23 depends upon Claim 22. Dependent Claims 7 and 23 more particularly define the carrier material as being from a group including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The separated entire contents of the harvested eggs are not dried before they are coated onto the dry feed carrier material. This avoids the reduction of the effectiveness of the IgY, IgM and IgA immunoglobulins caused by the process of drying the entire contents of the harvested eggs.

It would not have been obvious to one skilled in the art to make a microbial adherence inhibitor by the method of providing a dry feed carrier material and coating the dry feed carrier

material with the separated entire contents of the harvested eggs in view of the teachings of the combined references. Further, the Examiner has completely failed to show any motivation to combine the *Tokoro '895* reference with the six secondary references. There is certainly no "clear and particular" showing of motivation to combine.

I. Rejection of Claims 24-29 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Krause et al*, *Adalsteinsson et al '878* and *Betz et al '867*

Claims 24 to 29 include a dry feed carrier material and coating the dry feed carrier material with the separated entire contents of the harvested eggs. The entire contents of the separated eggs are not dried before coating the dry carrier material with said contents of the eggs.


Appellants' analysis, *supra*, concerning the primary reference, *Tokoro '895*, and secondary references, *Kaspers et al*, *Pimental '489*, *Stolle et al '018*, *Krause et al*, *Adalsteinsson et al '878* and *Betz et al '867*, are applicable to the rejection of Claims 24 to 29.

The inclusion of a dry feed carrier material and coating the material with the entire contents of harvested eggs is not shown or suggested by the prior art, either alone or in combination. Further, there is no "clear and particular" objective evidence of record showing motivation to combine the myriad references. The Examiner has again completely failed to show any motivation to combine his references.

The reversal of the examiner's rejection as to Claims 1, 3, 5-7 and 12-29 is requested.

Respectfully submitted,

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APPENDIX A

1. A microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by the method of:

A. Inoculating female chickens, in or about to reach their egg laying age, with a particular target colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the chickens of antibody to the target colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells; and

E. Drying said separated entire contents of said eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a colony-forming immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

3. The microbial adherence inhibitor according to Claim 1 wherein: said targeted colony-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilum*.

5. A microbial adherence inhibitor for administration to a living being to inhibit the adherence of a colony-forming immunogen in the digestive tract of the living being, said colony-forming immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* produced by the method of:

A. Inoculating female birds in or about to reach their egg laying age with the colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the birds of antibody to the colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells; and

E. Drying said separated entire contents of said eggs, said dried entire contents of said eggs when administered to the living being inhibiting the adherence of the colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

6. A microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by the method of:

A. Inoculating female chickens, in or about to reach their egg laying age, with a particular target colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the chickens of antibody to the target colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material; and

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

7. The microbial adherence inhibitor according to Claim 6 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

12. A microbial adherence inhibitor for administration to a living being to inhibit the adherence of a colony-forming immunogen in the digestive tract of the being produced by the method of:

A. Inoculating female birds in or about to reach their egg laying age with the colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the birds of antibody to the colony-forming immunogen, said antibody in the eggs including IgY

immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

- C. Harvesting the eggs laid by the birds;
- D. Separating the entire contents of said harvested eggs from the shells;
- E. Providing a dry food carrier material;
- F. Coating said dry food carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins, said colony-forming immunogens are from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

13. A microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of said food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P. anaerobius* produced by the method of:

- A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P. anaerobius*;
- B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs

including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the antibody-containing contents of said eggs from the shells;

and

E. Drying said entire contents of said eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

14. The microbial adherence inhibitor according to Claim 13 wherein: the drying of the separated entire contents of said eggs is achieved by coating dry feed carrier material with the entire contents of said eggs.

15. The microbial adherence inhibitor according to Claim 14 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

16. A microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of said food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen

to multiply, said protein-wasting immunogen is CS antigen from *C. sticklandii* produced by the method of:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C. sticklandii*;

B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to CS antigen from *C. sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells; and

E. Drying said entire contents of said eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

17. The microbial adherence inhibitor according to Claim 16 wherein: the drying of the separated antibody-containing contents of said eggs is achieved by coating dry feed carrier material with the entire contents of said eggs.

18. The microbial adherence inhibitor according to Claim 17 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

19. A microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of said food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C. aminophilium* produced by the method of:

- A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C. aminophilium*;
- B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to CA antigen from *C. aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
- C. Harvesting the eggs laid by the birds;
- D. Separating the entire contents of said harvested eggs from the shells; and
- E. Drying said entire contents of said eggs.

20. The microbial adherence inhibitor according to Claim 19 wherein: the drying of the separated entire contents of said eggs is achieved by coating dry feed carrier material with the entire contents of said eggs.

21. The microbial adherence inhibitor according to Claim 20 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

22. A microbial adherence inhibitor for administration to food animals to inhibit the adherence of targeted colony-forming immunogens in the rumen or intestinal tracts of said food animals produced by the method of:

A. Inoculating female birds, in or about to reach their egg laying age, with the particular target colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said eggs from the shells;

E. Providing a dry feed carrier material; and

F. Coating said dry feed carrier material with the entire contents of said eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

23. The microbial adherence inhibitor according to Claim 22 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

24. A microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of said food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P. anaerobius* produced by the method of:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen with *P. anaerobius*;

B. Allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material; and

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

25. The microbial adherence inhibitor according to Claim 24 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

26. A microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen of intestinal tracts of said food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C. sticklandii* produced by the method of:

- A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C. sticklandii*;
- B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to CS antigen from *C. sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
- C. Harvesting the eggs laid by the birds;
- D. Separating the entire contents of said harvested eggs from the shells;
- E. Providing a dry feed carrier material; and
- F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to

the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

27. The microbial adherence inhibitor according to Claim 26 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

28. A microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C. aminophilium* produced by the method of:

- A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C. aminophilium*;
- B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to CA antigen from *C. aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
- C. Harvesting the eggs laid by the birds;
- D. Separating the entire contents of said harvested eggs from the shells;
- E. Providing a dry feed carrier material; and
- F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire

contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

29. The microbial adherence inhibitor according to Claim 28 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

E-coli on normal egg head

EXHIBIT

A

EXHIBIT

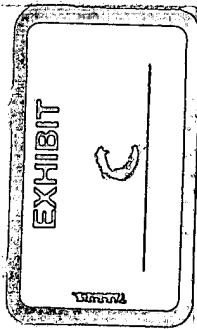
B

E-coli 0157:H7



BEST AVAILABLE COPY

Streptococcus bovis Normal Egg Bead



EXHIBIT

D

Strep. Bovis